

**CRITERIA FOR PRIOR AUTHORIZATION**

## PCSK9 Inhibitors

**PROVIDER GROUP** Pharmacy  
Professional

**MANUAL GUIDELINES** The following drugs require prior authorization:  
alirocumab (Praluent®)  
evolocumab (Repatha®)

**CRITERIA FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HoFH)** (must meet all of the following):

- Patient must have a diagnosis of homozygous familial hypercholesterolemia. This must be evidenced by:
  - Genotyping; or
  - Clinical diagnosis based on a history of untreated LDL-C > 500 mg/dl and one of the following:
    - Xanthoma prior to the age of 10 years
    - Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
- Patient must be at least 13 years old
- Must be used as adjunct to diet
- Must be used as adjunct to other LDL-lowering therapy (maximally tolerated stable therapy, or patient must have a contraindication or allergic reaction to other therapy)
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is evolocumab (Repatha®)
  - Dose must not be greater than 140 mg every 14 days

**CRITERIA FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH)** (must meet all of the following):

- Patient must have a diagnosis of heterozygous familial hypercholesterolemia. This must be evidenced by:
  - Genotyping; or
  - Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria
- Must be at least 18 years old
- Must be used as adjunct to diet
- Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)\*
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is:
  - Evolocumab (Repatha®)
    - Dose must not be greater than 140 mg every 14 days
  - Alirocumab (Praluent®)
    - Dose must not be greater than 150 mg every 14 days

Prior Authorization Criteria

**CRITERIA FOR PRIMARY HYPERLIPIDEMIA** (must meet all of the following):

- Patient must have a diagnosis of clinical atherosclerotic cardiovascular disease (diagnosis of CVD, MI, unstable angina, or previous ACS) and require additional lowering of LDL-cholesterol
- Must be at least 18 years old
- Must be used as adjunct to diet
- Must be used as adjunct to maximally tolerated stable, daily statin therapy (or patient must have a contraindication or allergic reaction to statins)\*
- Must be prescribed by or in consultation with a cardiologist or lipidologist
- Prescribed drug is:
  - Evolocumab (Repatha®)
    - Dose must not be greater than 140 mg every 14 days
  - Alirocumab (Praluent®)
    - Dose must not be greater than 150 mg every 14 days

**LENGTH OF INITIAL APPROVAL:** 3 months

**CRITERIA FOR RENEWAL** (must meet all of the following):

- Documentation that lipid lowering has occurred
- Documentation of continued adjunct diet changes and pharmacotherapy from initial approval
- Prescribed drug is:
  - Evolocumab (Repatha®)
    - Dose must not be greater than 140 mg every 14 days
  - Alirocumab (Praluent®)
    - Dose must not be greater than 150 mg every 14 days

**LENGTH OF RENEWAL APPROVAL:** 6 months

**\*Notes:**

- Clinical atherosclerotic cardiovascular disease includes, but is not limited to, a diagnosis of cardiovascular disease (CVD) or a previous acute coronary syndrome (ACS) (e.g., myocardial infarction, ischemic stroke, unstable angina)
- For HeFH and Primary Hyperlipidemia patients who require adjunct therapy for High LDL Levels (LDL-C > 160 mg/dl), a trial of a stable statin therapy and failure of multiple statins at maximum dose must be employed
  - Stable statin therapy is defined as the patient being at a stable dose for at least 4 weeks
  - Combination therapy with covered alternative agent(s) is required if maximum statin dosage did not achieve efficacious level (e.g. ezetimibe, bile acid sequestrants, or other antilipemic agent or therapy)
  - Baseline lab prior to any treatment and labs after all previous treatments showing inadequate control on statins
  - For intolerance to statins, trial and failure of 2 statins at lower dose must be utilized. Specific intolerance must be documented and temporally related to statin treatment.

Prior Authorization Criteria

- If intolerance is due to muscle pain, attach creatinine kinase labs checking for rhabdomyolysis.
- For Repatha®, requests of 420mg every 28 days, clinical justification must be provided as to why the 140mg every 14 day dosing regimen was not sufficient/indicated.